IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A pharmaceutical aerosol formulation to be administered by a pressurized metered dose ~~inhalers~~ inhaler, which comprises:

an active ingredient selected from the group consisting of salmeterol, [[or]] a stereoisomer thereof, and a physiologically acceptable salt ~~and solvate~~ thereof, in solution in a propellant system, said propellant system ~~consisting of~~ comprising a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water,

wherein said ~~characterised in that the amount of the~~ cosolvent is present in an amount which is no more than 35% w/w based on the total weight of [[the]] said formulation, and

wherein said formulation has a pH of 2.5 to 5.5, and

wherein said pH of said formulation has been adjusted by addition of a mineral acid.

Claim 2 (currently amended): A pharmaceutical formulation according to claim 1, ~~wherein the co-solvent is~~ which comprises at least one member selected from the group consisting of a lower alkyl (C1-C4) ~~alcohols~~ alcohol, ~~polyols~~ a polyol, a polyalkylene ~~glycols~~ glycol, a (poly)alkoxy ~~derivatives~~ alcohol, and ~~their combinations~~ mixtures thereof.

Claim 3 (currently amended): A pharmaceutical formulation according to claim 2, which comprises ~~wherein the cosolvent is~~ ethanol.

Claim 4 (currently amended): A pharmaceutical formulation according to claim 3, wherein ~~the amount of~~ said water is present in an amount of ~~from~~ 0.5% to 5% w/w and said ethanol is present in an amount of no more than 25% w/w.

Claim 5 (currently amended): A pharmaceutical formulation according to ~~claims 1-4~~ claim 1, wherein ~~the amount of~~ said water is present in an amount up to 3% w/w.

Claim 6 (currently amende): A pharmaceutical formulation according to ~~claims 1-5~~ claim 1, wherein ~~the~~ a fraction of particles equal to or less than 1.1 μm delivered on actuation of [[the]] an inhaler, ~~the superfine fraction~~ which contains said formulation, is higher than or equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade Impactor, relative to the content of the stages ~~S6-AF~~ S3-AF of an Andersen Cascade Impactor~~, according to the method referred to in the description on page 16 lines 16 to 24~~.

Claim 7 (currently amended): A pharmaceutical formulation according to ~~claims 1-6~~ claim 1, wherein ~~the superfine fraction~~ said fraction of particles equal to or less than 1.1 μm delivered on actuation of said inhaler is higher than 40%.

Claim 8 (currently amended): A pharmaceutical formulation according to ~~claims 1-7~~ claim 1, which comprises ~~wherein the active ingredient is~~ salmeterol xinafoate.

Claim 9 (currently amended): A pharmaceutical formulation according to claim 8, ~~wherein the active ingredient is~~ which comprises said salmeterol xinafoate in a concentration of ~~between~~ 0.005 ~~and~~ to 0.15% w/v.

Claims 10-11 (canceled).

Claim 12 (currently amended): A pharmaceutical formulation according to ~~any preceding~~ claim 1, ~~wherein the propellant includes~~ which comprises one or more hydrofluoroalkanes ~~[HFAs]~~ selected from the group ~~comprising~~ consisting of HFA 134a, [[and]] HFA 227, and mixtures thereof.

Claim 13 (currently amended): A pharmaceutical formulation according to ~~claims 1-12 comprising~~ claim 1, which comprises 0.04% w/v salmeterol, 15% w/w ethanol, and 2% w/w water.

Claim 14 (currently amended): A pharmaceutical formulation according to ~~any preceding~~ claim 1, filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.

Claim 15 (currently amended): A pharmaceutical formulation according to ~~any preceding~~ claim ~~comprising a further~~ 1, which further comprises at least one active ingredient selected from the ~~class of steroids such as~~ group consisting of beclomethasone dipropionate, fluticasone propionate, ciclesonide, budesonide, the ~~and its~~ 22R-epimer of budesonide, ~~or anticholinergic atropine-like derivatives such as~~ ipratropium bromide, oxitropium bromide, and tiotropium bromide.

Claim 16 (currently amended): A method of preparing [[the]] a pharmaceutical formulation according to ~~formulations of claims 1-15~~ claim 1, [[the]] said method comprising:

(a) preparing [[of]] a solution of one or more active ingredients in one or more co-solvents;

(b) optionally adding a proper amount of water and adjusting the pH of the solution;

(c) filling ~~of the~~ a device with said solution;

(d) crimping said device with ~~valves~~ a valve and gassing; and[[.]]

(e) adding a propellant containing a hydrofluoroalkane ~~(HFA)~~.

Claim 17 (currently amended): A method according to claim 16, wherein [[the]] said device in provided with a valve actuator whose orifice diameter is 0.22 mm.

Claim 18 (currently amended): A ~~pharmaceutical formulation according to any one of claims 1 to 17~~ method for the treatment of a respiratory ~~diseases~~ disease, comprising administering an effective amount of a pharmaceutical formulation according to claim 1 to a subject in need thereof.

Claim 19 (currently amended): A ~~pharmaceutical formulation~~ method according to claim 18, wherein said ~~in which the~~ respiratory disease is asthma or ~~Chronic~~ chronic obstructive pulmonary disease ~~(COPD)~~.

Claim 20 (currently amended): A ~~pharmaceutical formulation~~ method according to claim 19, wherein said ~~in which the~~ respiratory disease is due to obstruction of ~~the~~ peripheral airways as a result of inflammation or mucus hypersecretion.

Claim 21 (currently amended): A ~~pharmaceutical formulation~~ method according to claim 18, wherein [[the]] said respiratory disease is pulmonary edema or a surfactant-deficiency related disorder ~~such as acute lung injury (ALI) or acute respiratory distress syndrome (ARDS)~~.

Claim 22 (new): A method according to claim 18, wherein said respiratory disease is acute lung injury or acute respiratory distress syndrome.